

Rejections Under 35 U.S.C. § 112, Second Paragraph

Claims 1, 5, 10, 22, 25, 29, 30, 39, 40, 50, 56, 57, 61, 64, and 71 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter regarded as the invention.

Claims 1, 5, 10, 22, 30, 39, 40, 57, 61, and 64 have each been amended to overcome the section 112, second paragraph rejections. The amendments to each of these claims have been made without prejudice or disclaimer and are not believed to change the scopes of these claims.

In addition, with respect to the recitation of “a second end” in claim 22, it is respectfully submitted that no prior recitation of “second end” had been made and that claim 22, therefore, properly sets forth the element as “a second end”.

It is respectfully submitted that no structural or functional relationship need be provided between the “reaction region” recited in claims 7, 8, and 9 and the elements “a stationary phase” in claim 25 and “a capture substrate” in claim 26. Neither claim 25 nor claim 26 depends from claim 7, claim 8, or claim 9. Thus, the invention as recited in claims 25 and 26 need not include the elements recited in claims 7, 8, or 9. As a result, it is not necessary to provide a structural or functional cooperative relationship between any of the elements recited in claims 7, 8, and 9 and the elements recited in claims 25 and 26, which are only related to claims 7, 8, and 9 by their dependency from the same independent claim.

Claims 29, 50, and 56 were rejected under section 112, second paragraph, because the phrase “at least a portion of” was considered by the Office to be indefinite. It is respectfully submitted that the phrase “at least a portion of”, which describes the amount of a first porous region over which a sealing element is situated, is not indefinite as “at least a portion” clearly indicates that a sealing element may be situated over all or only a part of the first porous region. The requirement of further specificity, such as the exact distance or the percentage of the total length or width of the capillary column over which the sealing element is situated would be unnecessarily limiting.

In the rejection of claim 40 under section 112, second paragraph, it was stated that the term “an end” is indefinite as not “specifically defin[ing] which end of the capillary column the valve is in communication with”. It is respectfully submitted that a capillary column has a finite

number of ends and that by reciting “an end”, claim 40 clearly indicates that a valve communicates with at least one of the ends of the capillary column. As the relationship between the valve and the capillary column has been set forth in claim 40, further specificity is not needed, nor should such be required.

Claim 71 was rejected under section 112, second paragraph for similar reasons to the rejections of claims 29, 50, and 56. Again, the “capture substrate” recited in claims 66, 67, 68, and 69 need not be related in any way to the “reaction region” recited in claim 71 since claim 71 is only related to claims 66, 67, 68, and 69 by virtue of its dependency from the same independent claim.

For these reasons, it is respectfully requested that each of the 35 U.S.C. § 112, second paragraph rejections that were set forth in the outstanding Office Action be withdrawn.

Rejections Under 35 U.S.C. § 102

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Brothers v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). The identical invention must be shown in as complete detail as is contained in the claim. *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989).

Isaka

Claims 1, 3, 4, 7-9, 12, 18-20, 25, 26, 29-32, 34, 35, 38, 39, 50-52, 56, 64, 66, 69, 71, and 73 were rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent 5,482,598 to Isaka et al. (hereinafter “Isaka”).

Isaka teaches a chromatographic separation device that includes a silicon substrate and a single porous microchannel formed therein.

Claim 1, as amended and presented herein, recites a sample separation apparatus that includes a substrate, matrices formed in the substrate and comprising at least two porous regions that extend at least partially across the substrate. The sample separation apparatus of claim 1

also includes at least one detector fabricated on the substrate and associated with at least one of the at least two porous regions.

Isaka lacks disclosure of more than one matrix and of at least two porous regions that extend at least partially across a substrate thereof. Moreover, Isaka fails to disclose a detector that is fabricated on the substrate and associated with a porous region formed therein. Accordingly, it is respectfully submitted that Isaka does not anticipate the subject matter recited in amended claim 1 and that amended claim 1 is, therefore, allowable under 35 U.S.C. § 102(b).

Claims 3, 4, 7-9, 18-20, 25, 26, and 29 are each allowable, among other reasons, as depending either directly or indirectly from claim 1, which should be allowed.

Claim 12 has been canceled without prejudice or disclaimer.

Claims 8 and 26 are each further allowable since the enzyme disclosed in Isaka is not a capture component or capture substrate. As those of skill in the art are aware, an enzyme reacts with a substrate in a manner that detectably alters the substrate. By way of contrast, a capture component or capture substrate reacts with an analyte by capturing the analyte, and need not substantially alter the analyte.

Independent claim 30, as amended and presented herein, recites a separation apparatus that includes a substrate, at least two capillary columns formed in the substrate, and a detector situated adjacent at least one of the capillary columns.

Isaka does not disclose a separation apparatus with at least two capillary columns. Therefore, it is respectfully submitted that Isaka does not anticipate amended claim 30 and that amended claim 30 is, therefore, allowable under 35 U.S.C. § 102(b).

Claims 31, 32, 34, 35, 38, 39, and 50 are each allowable, among other reasons, as depending either directly or indirectly from claim 30, which should be allowed.

In addition, claim 35 is allowable since the enzyme disclosed in Isaka is not a capture substrate. As those of skill in the art are aware, an enzyme reacts with a substrate in a manner that detectably alters the substrate. By way of contrast, a capture substrate reacts with an analyte by capturing the analyte, and need not substantially alter the analyte.

Amended independent claim 51 recites a miniature chromatograph that includes a substrate and porous matrices formed in the substrate and comprising at least two capillary columns.

As Isaka lacks disclosure of a miniature chromatograph including substrate with more than one porous matrix formed therein and at least two capillary columns formed by the porous matrices, it is respectfully submitted that claim 51, as amended and presented herein, is allowable over Isaka under 35 U.S.C. § 102(b).

Claims 52 and 56 are each allowable, among other reasons, as depending from claim 51, which should be allowed.

Independent claim 64, as amended and presented herein, recites an analyte detection apparatus that includes a substrate comprising silicon and matrices formed in the substrate and comprising at least two porous columns continuous with a surface of the substrate.

Isaka does not disclose an analyte detection apparatus with more than one porous column. Accordingly, it is respectfully submitted that Isaka does not anticipate the subject matter recited in amended claim 64 and that amended claim 64 is, therefore, allowable under 35 U.S.C. § 102(b).

Claims 66, 69, 71, and 73 are each allowable, among other reasons, as depending either directly or indirectly from claim 64, which should be allowed.

Claim 66 is additionally allowable since Isaka includes no disclosure of a capture substrate. As explained previously herein, an enzyme reacts with a substrate in a manner that detectably alters the substrate, while a capture substrate reacts with an analyte by capturing the analyte, and need not substantially alter the analyte.

For the foregoing reasons, it is respectfully requested that the Office withdraw the 35 U.S.C. § 102(b) rejections of claims 1, 3, 4, 7-9, 18-20, 25, 26, 29-32, 34, 35, 38, 39, 50-52, 56, 64, 66, 69, 71, and 73 as being anticipated by Isaka.

Northrup

Claims 1, 18, 22-24, 30 and 42 were rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent 5,882,496 to Northrup et al. (hereinafter "Northrup").

Northrup discloses, among several other things, a electrophoretic separation device that includes porous columns formed internally within a silicon substrate. Electrodes are positioned at opposite ends of the substrate so as to facilitate the movement of the constituents of a sample along the lengths of the columns.

Amended claim 1 recites a sample separation apparatus that includes a substrate, at least two porous regions formed in the substrate, and at least one detector fabricated on the substrate and associated with at least one of said at least two porous regions.

As Northrup lacks disclosure of a sample separation apparatus with at least one detector fabricated on the substrate, it is respectfully submitted that amended claim 1 is allowable over Northrup.

Claims 18 and 22-24 are each allowable, among other reasons, as depending either directly or indirectly from claim 1, which should be allowed.

Independent claim 30, as amended and presented herein, recites a separation apparatus that includes a substrate, at least two capillary columns formed in the substrate, and a detector fabricated on the substrate and situated adjacent at least one of the capillary columns.

By way of contrast with amended claim 30, Northrup fails to disclose a detector that is fabricated on the substrate of a separation apparatus. Thus, it is respectfully submitted that, under 35 U.S.C. § 102(b), Northrup does not anticipate the subject matter recited in amended claim 30.

Claim 42 is allowable, among other reasons, as depending from claim 30, which should be allowed.

For these reasons, it is respectfully requested that the 35 U.S.C. § 102(b) rejections of claims 1, 18, 22-24, 30, and 42 be withdrawn.

Rejections Under 35 U.S.C. § 103(a)

To establish a *prima facie* case of obviousness under 35 U.S.C. § 103(a), three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Third, the cited prior art reference must teach or suggest all of the claim limitations. Furthermore, the suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on Applicant's disclosure.

Isaka in View of Miura

Claims 14-17, 21, 40, 41, 43, 44, 54, 55, and 70 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Isaka in view of U.S. Patent 5,132,012 to Miura et al. (hereinafter "Miura").

The teachings of Isaka were summarized previously herein.

Miura discloses, among other things, a small-scale liquid chromatograph including a silicon substrate, a single, coiled column formed in the substrate, and a detector, such as a field effect transistor, formed on the substrate, adjacent the column.

Claims 14-17 and 21 are each allowable, among other reasons, as depending either directly or indirectly from claim 1, which should be allowed for the reasons provided previously herein.

Claim 16, which recites that the sample separation apparatus include a processor on the substrate, is further allowable as Miura merely teaches or suggests the possible association of a processor with the chromatograph, not that such a processor would actually be positioned on the substrate.

Claim 17 is additionally allowable since Miura lacks any teaching or suggestion of a memory device on the substrate. As those of skill in the art are aware, memory devices could not control the operation of a chromatograph as would the control device (i.e., a controller or processor) taught in Miura.

In addition, claim 21 is allowable since Miura fails to teach or suggest a vacuum source in operative communication with the column of the chromatograph taught in Miura. Rather, it is Applicant's understanding that Miura only teaches or suggests the use of positive pressure to facilitate the movement of a sample through the column. *See, e.g.*, Miura, col. 10, lines 1-34.

Claims 40, 41, 43, and 44 are each allowable, among other reasons, as depending either directly or indirectly from claim 30, which should be allowed.

Claim 41 is also allowable since Miura fails to teach or suggest a vacuum source in operative communication with the column of the chromatograph taught in Miura. Rather, it is Applicant's understanding that Miura only teaches or suggests the use of positive pressure to facilitate the movement of a sample through the column. *See, e.g.*, Miura, col. 10, lines 1-34.

In addition, claim 44 is additionally allowable since Miura neither teaches nor suggests that the chromatograph thereof includes a memory device on its substrate. As those of skill in the art are aware, memory devices could not control the operation of a chromatograph as would the control device (i.e., a controller or processor) taught in Miura.

Claims 54 and 55 are each allowable, among other reasons, as depending from claim 52, which should be allowed.

Claim 70 is allowable, among other reasons, as depending from claim 64, which should be allowed.

In light of the foregoing reasons, it is respectfully requested that the Office withdraw the 35 U.S.C. § 103(a) rejections of claims 14-17, 21, 40, 41, 43, 44, 54, 55, and 70 as being rendered obvious by the combination of Isaka and Miura.

Isaka in View of Wang

Claims 13, 21, 41, 53, and 70 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Isaka in view of U.S. Patent 5,663,488 to Wang et al. (hereinafter "Wang").

The teachings of Isaka are discussed previously herein with respect to the 35 U.S.C. § 102 rejections asserted by the Office.

Wang teaches a thermal isolation system that includes, among other things, a chamber within which temperature and pressure may be controlled. A separation device, such as a miniature chromatographic column, may be disposed within the chamber.

Claims 13 and 21 are allowable, among other reasons, as depending from indirectly from claim 1, which should be allowed.

In addition, claim 13 is allowable since Wang does not teach or suggest the inclusion of a thermal detector on a substrate in which the chromatography column thereof is formed. Rather, the thermal detector taught in Wang is a thermal conductivity detector that is associated with the chamber for controlling the temperature and pressure therein.

Claim 21 is further allowable since Wang does not teach or suggest a vacuum source operatively in communication with an end of the chromatography column thereof. Rather, the vacuum of Wang, which is discussed, for example, at col. 1, line 63, to col. 2, line 4, and col. 2, lines 29-41, thereof, is used to vary the pressure within the chamber and would, therefore, be applied evenly across an entire column positioned within the chamber.

Claim 41 is allowable as depending from claim 30, which should be allowed, and further because Wang fails to teach or suggest a vacuum source operatively in communication with an end of a chromatography column.

Claim 53 is allowable as depending from claim 52, and also since Wang lacks any teaching or suggestion of the inclusion of a thermal detector on a substrate in which the chromatography column is formed.

Claim 70 is allowable as depending from claim 64, and also because Wang does not teach or suggest the inclusion of a thermal detector, a field effect transistor, or a current detector on a substrate in which the chromatography column is formed.

For the foregoing reasons, it is respectfully requested that the Office withdraw the 35 U.S.C. § 103(a) rejections of claims 13, 21, 41, 53, and 70 as being unpatentable in view of the teachings of Isaka and Wang.

Isaka in View of Turner

Claims 33, 74, and 105-107 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Isaka in view of U.S. Patent 5,885,869 to Turner et al. (hereinafter “Turner”).

35 U.S.C. § 103(c) provides:

Subject matter developed by another person, which qualifies as prior art under one or more of subsections (e), (f), and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

As the referenced application, which is a Continued Prosecution Application of U.S. Ser. No. 09/177,814, was filed on April 18, 2000, the provisions of 35 U.S.C. § 103(c) apply.

The referenced application is entitled to priority, under 35 U.S.C. § 120, of the October 23, 1998, filing date of U.S. Ser. No. 09/177,814. Accordingly, Turner, which did not issue until March 23, 1999, and which is owned by Micron Technology, Inc., to which the referenced application has also been assigned, qualifies as prior art under 35 U.S.C. § 102(e). Accordingly, Isaka and Turner cannot be properly combined under 35 U.S.C. § 103(a) to render the subject matter recited in any of the claims of the referenced application obvious.

35 U.S.C. § 103(c).

Therefore, it is respectfully requested that the Office withdraw the 35 U.S.C. § 103(a) rejections of claims 33, 74, and 105-107 as being rendered unpatentable by the combination of Isaka and Turner.

Isaka or Northrup in View of Turner and Further in View of Sunzeri and Swedberg

Claims 5, 6, 10, 11, 27, 28, 36-38, 45-49, 57-63, 67, 68, and 72 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Isaka or, if necessary, Northrup in view of Turner and in further view of U.S. Patent 5,536,382 to Sunzeri (hereinafter “Sunzeri”) and U.S. Patent 5,571,410 to Swedberg et al. (hereinafter “Swedberg”).

Again, the referenced application, which is a Continued Prosecution Application of U.S. Ser. No. 09/177,814, was filed on April 18, 2000. Thus, the provisions of 35 U.S.C. § 103(c) apply.

The referenced application is entitled to priority, under 35 U.S.C. § 120, of the October 23, 1998, filing date of U.S. Ser. No. 09/177,814. Accordingly, Turner, which did not issue until March 23, 1999, and which is owned by Micron Technology, Inc., to which the referenced application has also been assigned, qualifies as prior art under 35 U.S.C. § 102(e). Accordingly, Turner cannot be properly combined under 35 U.S.C. § 103(a) with any other references (i.e., either Isaka or Northrup in view of Sunzeri and Swedberg) to render the subject matter recited in any of the claims of the referenced application obvious. 35 U.S.C. § 103(c). Therefore, it is respectfully requested that the Office withdraw the 35 U.S.C. § 103(a) rejections of claims 5, 6, 10, 11, 27, 28, 36-38, 45-49, 57-63, 67, 68, and 72 as being rendered unpatentable by either Isaka or Northrup in view of Turner, and further in view of Sunzeri and Swedberg.

CONCLUSION

It is respectfully submitted that claims 1, 3-11, 13-44, 46, 48-64, 66-74, and 105-107 are in condition for allowance. An early indication of such and that the case be passed for issue are respectfully solicited. If any issues preventing the allowance of any of these claims that may be resolved by a telephone conference remain, the Office is respectfully invited to contact the undersigned at the telephone number provided below.

Respectfully submitted,



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